IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1713

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Diane Frauchiger
Signature

April 26 2004
Date of Signature

In re

Patent Application of

Khalid Mentak

Application No. 09/917,971

Confirmation No. 1604

Filed: July 30, 2001

Examiner: Zalukaeva, Tatyana, Ph.D.

"WATER PLASTICIZED HIGH REFRACTIVE INDEX POLYMER FOR OPHTHALMIC APPLICATIONS"

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Concerning the above-referenced patent application, the Applicants have appealed from the final rejection dated May 27, 2003. Applicants are submitting this Appeal Brief in triplicate in support of their appeal. Applicants are also enclosing a check in the amount of $330.00 for the payment of the official filing fee for this Appeal Brief. Accompanying this brief is a request for a three month extension of time and the appropriate fee extending the period of response to April 26, 2004. Applicants respectfully submit that this brief is timely filed.

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1. Real Parties-in-Interest. The real party-in-interest are Surgidev Corporation doing business as Advanced Vision Science, Inc. a California corporation, having its primary place of business at 5743 Thornwood Drive, Goleta, California 93117. Assignment recorded September 24, 1999 at Reel/Frame 010265/0822.

2. Related Appeals and Interferences. There are no appeals or interferences related to this appeal.

3. Status of Claims. The present application, U.S. Patent Application No. 09/917,971 was filed on July 30, 2001. The application is a divisional application of U.S. Patent Application No. 09/358,757 filed July 22, 1999, now U.S. Patent No. 6,281,319, which claims priority to U.S. Provisional Application No. 60/128,751 filed April 12, 1999. Claims 1-42 were originally filed with this application. Claims 1-32 and 38-42 were cancelled with a preliminary amendment which was filed along with the application, leaving claims 33-37 as the original pending claims of the application. No further claim amendments have been made. Thus, claims 33-37 are pending (see the attached Appendix). Claims 33-37 are the subject of this appeal.

4. Status of Amendments. A preliminary amendment was filed along with the Application on July 30, 2001 canceling claims 1-32 and 38-42. An Office Action issued August 19, 2002 indicated that these amendments were entered. A final Office Action was issued on May 27, 2003 rejecting claims 33-37. Applicants filed a response under 37 CFR § 1.116 along with a declaration of inventor Khlaid Mentak , Ph.D. under 37 CFR § 1.132 on November 24, 2003. The Advisory Action issued January 22, 2004 indicated that the declaration was considered and entered, but apparently not deemed to be persuasive.

5. Summary of the Invention. In the following summary of the invention, references to page and line numbers are with reference to the application filed on July 30, 2001.

The present invention, specifically claims 33-37 on appeal, relate to a method of manufacturing an intraocular lens (claim 33 and page 2, line 24). The intraocular lens is made from a polymeric material that is hard enough to machine at room temperature, but can be hydrated to be foldable by a controlled hydrating process. (page 2, lines 29-31). The intraocular lens is hydrated to a flexible state with minimal water uptake. The relatively low water uptake allows efficient hydration without affecting mechanical or optical properties and without changing the dimensions or the refractive index of the foldable lens (page 2, lines 31-34). The intraocular lens made from the copolymer has the same desired dimensions in it's rigid form, as it does in it's hydrated form (claim 33 and page 9, lines 26-27). Suitably the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10% (claim 34 and page 11, lines 9-12). Also, the hydrated copolymer has an equilibrium water concentration less than about 10 weight percent, and a refractive index greater than about 1.55 (claim 33 and page 9, lines 9-10).

The copolymer is produced from a polymerization reaction of first, second and third monomeric components. (claim 33 and page 3, lines 30-31). The first monomeric component includes an aryl acrylate or an aryl methacrylate. (claim 33 and page 4, lines 23 to page 5, line 24). The second monomeric component, which is not an acrylate, includes a monomer having an aromatic ring with a substituent having at least one site of ethylenic unsaturation. (claim 33 and page 6, lines 1-20). The third monomeric component commprises a high water content hydrogel-forming monomer. (claim 33 and page 6, lines 33-34). High water content hydrogel forming monomers are materials which are hard or rigid when dry, and absorb a large amount of water (e.g. up to 20%-70% by weight) when hydrated, and lowers the refractive index of the material (page 1, line 27). The copolymer may also contain a crosslinking agent. (page 7, line

19). The crosslinking agent can include diacrylate compounds, including ethylene glycol dimethacrylate (EGDM), diethylene glycol dimethacrylate, polyethylene glycol dimethacrylate, alkyl methacrylate, 1-3-propanedioldimethacrylate allymethacrylate, 1,6-hexanediol dimethacrylate, 1,3-butanediol dimethacrylate, 1,4-butanediol dimethacrylate as well as, divinyl compounds including divinyl hydrocarbons and divinyl benzene, and the like. (page 8, lines 1-6).

The intraocular lenses are made from the copolymer by combining the monomeric components and a crosslinker at a reduced pressure (page 12, line 6-8), The monomer solution is mixed, filtered and injected into a sheet mold. The mold is then cured to a hard polymer sheet (page 12, lines 10-15). Intraocular lens are cut from the rigid copolymer sheet and are polished (claim 37 and page 12, lines 16-20). At this stage the intraocular lenses are still hard and non-foldable. The lens are then hydrated by placing the copolymer in an aqueous solution. The temperature of the aqueous solution is then gradually increased to about 40°C. The aqueous solution is held at this temperature for at least about 10 minutes. The temperature of the aqueous solution is then again gradually increase to about 60°C, and maintained at this temperature for at least about one hour. The temperature of the aqueous solution is then gradually decreased to about room temperature (claim 36 and page 12, lines 19-29).

Suitably the lenses produced by the method are a 20 diopter lens and have a central thickness less than about 0.4mm (claim 35 and page 10, lines 23-25).

6. Issues. The issues presented in this appeal are:

i) Whether claims 33-35 and 37 are unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 4,731,079 issued to Stoy (hereinafter "Stoy").

ii) Whether claims 35-36 are unpatentable under 35 U.S.C. § 103(a) over Stoy

7. Grouping of Claims.

Claims 33 and 37 stand or fall as a group.

Claim 34 stands or falls as a group.

Claim 35 stands or falls as a group.

Claim 36 stands or falls as a group.

Claim 33 relates to a method of making an intraocular lens comprising providing a rigid, hydratable copolymer comprising three monomeric components. The copolymer has a glass transition temperature greater than room temperature. A rigid intraocular having the desired dimensions of the lens is formed, the lens being hydrated to a foldable state and having an equlibrium concentration less than about 10 weight percent and a refractive index greater than about 1.55. Claim 37 depends from claim 33 and contains the limitation that the rigid intraocular lens is formed by cutting a lens from a rigid sheet of the copolymer, and polishing the lens. Appellants submit that claims 33 and 37 are separately patentable over claims 34-36.

Claim 34 depends from claim 33 and relates to a method of making an intraocular lens wherein the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10%. None of the other pending claims contain such a limitation. Additionally, the cited prior art reference Stoy fails to teach or suggest such a feature. Furthermore the Examiner has failed to argue that the Stoy reference has met such a limitation. Appellants submit that claim 34 is separately patentable over claims 33 and 35-37.

Claim 35 depends from claim 33 and relates method of making an intraocular lens wherein the intraocular lens is a 20 diopter lens and has a central thickness less than about 0.4 mm. None of the other pending claims contain such a limitation. Additionally, the cited prior art

reference Stoy fails to teach or suggest such a limitation where the lens has a refractive index greater than about 1.55. Appellants submit that claim 35 is separately patentable over claims 33-34 and 36-37.

Claim 36 depends from claim 33 and relates to a method of making an intraocular lens wherein the copolymer is hydrated by a certain method. None of the other pending claims contain such a limitation. Additionally, the cited prior art reference Stoy fails to teach or suggest such a limitation. The specific limitations relating to hydration are important to obtain a hydratable lens with the claimed properties. Appellants submit that claim 34 is separately patentable over claims 33-35 and 37.

8. Argument

I. Claims 33, 34 and 37 are patentable over 35 U.S.C. § 102(b) in view of Stoy.

The Patent Examiner has taken the position that Appellants claims 33, 34 and 37 are anticipated by Stoy.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Stoy reference fails to disclose every element of the claims 33, 34 and 37. Specifically, the Stoy reference fails to disclose a third monomeric component which comprises a "high water content hydrogel-forming monomer." (See claim 33).

Claim 33 is an independent claim upon which claims 34 and 37 directly depend. Claim 34 and 37 therefore contain all of the elements of claim 33. Claim 33 contains the limitation, among others, of providing a rigid, hydratable copolymer comprising three monomeric components. (See claim 33). The third monomeric component comprises "a high water content hydrogel-forming monomer." (See claim 33). This limitation specifies that the third monomeric component alone, when polymerized, would form a hydrogel. The specification of the application discloses that high water content hydrogel forming monomers are:

> "Materials [which] are hard or rigid when dry, and absorb a large amount of water (e.g. up to 20%-70% by weight) when hydrated, which lowers the refractive index of the material" (see page 1, line 27 of the specification).

Specific examples of such materials are set forth in Example 1 of the application.

The Examiner argues that Stoy, in it's Example II, discloses a method of making an intraocular lens (IOL) which reads on the limitations of claims 33, 34 and 37. Example II of Stoy discloses that 85 grams of benzyl Acrylate, 15 grams of styrene and 0.35 grams of tetraethyleneglycol-bis-metharylate were polymerized under nitrogen by means of 0.075 grams of benzoylperoxide. The Examiner argues that the claimed "first monomeric" component of claim 33 corresponds to the benzyl Acrylate, the "second monomeric component" of claim 33 corresponds to the styrene, and the "third monomeric component" of claim 33 corresponds to the tetraethyleneglycol-bis-metharylate (also referred to as tetraethyleneglycol-dimetharylate "TEGDMA"). The Examiner thus contends that TEGDMA is considered a hydrogel forming monomer. The Examiner cited in the final Office Action that U.S. Patent No. 5,453,530 issued to Byerley (hereinafter "Byerley") and U.S. Patent No. 4,962,170 Chromecek (hereinafter "Chromecek") discloses that TEGDMA is a hydrogel forming monomer. Appellants respectfully

submit that the Examiner is incorrect in her assertion that TEGDMA is high water content hydrogel forming monomer as set forth in claim 33.

The Stoy reference fails to contain any teaching or suggestion that TEGDMA is a high water content forming monomer, and the Examiner has not made any assertion that the reference does so. The Examiner has contended, however, that the TEGDMA used in Stoy is a high water content forming monomer in light of the teachings of Byerley and Chromecek. It should be noted, however, that the Examiner has not made any statutory rejection based on Byerley or Chromecek.

It appears the Examiner is confusing the limitation in claim 33 that the third monomeric component itself is a "high water content hydrogel forming monomer" with the situation where a copolymer formed with the monomer is a hydrogel forming composition. TEGDMA itself is a crosslinking agent, not a "high water content hydrogel forming monomer". Nowhere in Stoy, Byerley or Chromecek does it disclose that TEGDMA, when polymerized alone, is a hydrogel forming monomer. Appellants argued the lack of teaching or suggestion by Stoy, and the error of the Examiners application of the Byerley and Chromecek references in the their response filed on November 24, 2003 and in the declaration of inventor Khalid Mentak also filed on November 24, 2003.

In the declaration of Dr. Mentak it was noted that:

> "...the Stoy patent does not disclose all of the elements and limitations of the claimed methods of the presently claimed invention. Specifically, Stoy does not disclose or suggest, inter alia, a method of manufacturing an intraocular lens wherein a rigid, hydratable copolymer is provided, and wherein the third monomeric component of the copolymer, comprises a high water content hydrogel-forming monomer" (see paragraph 7 of the Mentak Declaration).

Dr, Mentak went on to note that:

"In Byerley, the patent describes the use of TEGDMA in conjunction with thioacrylic and thiomethacrylic acids to form hydogels In this instance, TEGDMA is used as a crosslinking agent the same way it is used with other hydrophilic monomers to form hydrogels. In my opinion, there is nothing in the section highlighted by the examiner that suggests that TEGDMA, polymerized alone or with another crosslinker, can yield a hydrogel" (see paragraph 17 of the Mentak Declaration).

Dr. Mentak also noted that:

"Chromecek teaches a method of making highly adsorptive polymers. The key element of this invention is to create highly crosslinked polymeric particles that retain certain liquids by surface adsorption, but not bulk absorption. A powder with small particle size was preferred for increased surface area and hence enhanced superficial adsorption volume. The particles are not made highly porous to minimize swelling by liquid absorption. More specifically, TEGDMA as monomer was selected for this invention to produce highly crosslinked non-swellable polymers, but with the ability to adsorb water on particle surfaces. This reinforces the point that TEGDMA is not hydrogel forming" (see paragraph 18 of the Mentak Declaration).

Dr. Mentak noted that for a monomer to be considered hydrogel forming:

"A monomer needs to have certain properties in order to form a hydrogel in a homopolymer state. The monomer needs to have hydrophilic groups capable of binding and retaining water as a solute. More importantly, such moieties need to remain available for water molecules after polymerization. The hydrophilic character of the monomer decides the thermodynamic feasibility of water diffusion and retention by a polymer network. However, hydrophilicity is not sufficient to ensure that a monomer is hydrogel forming. The monomer must also allow water diffusion into the polymer network. Water diffusion in crosslinked polymer networks is based on the free volume theory, which postulates that polymer systems demonstrate the presence of void space or unoccupied volume. Free volume is a result of packing irregularities and long-range monomer interactions which give rise to excluded volume effect" (see paragrah 9 of the Mentak Declaration).

Dr. Mentak went on to note that:

"The greater the crosslink density, or concentration of crosslinking agent, the smaller the mesh size of the polymer network and the lower the equilibrium water content (EWC). Polymerizing a crosslinking agent such as TEGDMA alone would create such a tight polymer network that water molecules cannot diffuse into the bulk of the polymer. Such materials cannot absorb or hold water.

> Because of the hydrophilic nature of the monomer, water may adsorb to the surface of the polymer, but will not diffuse into the bulk of the material. Such polymers do not fit the definition of a hydrogel" (see paragraph 15 of the Mentak Declaration).

The Examiner has failed to comment on or submit evidence refuting the assertions of Dr. Mentak that TEGDMA is not a hydrogel forming monomer. The Examiner has simply maintained her position that Stoy teaches the use of TEGDMA, and the TEGDMA is a high water content hydrogel forming monomer based on the teachings of Byerley and Chromecek. As discussed above, Stoy teaches the use of TEGDMA, and Byerley and Chromecek disclose that TEGDMA can be used with other monomers to produce a hydrogel forming copolymer. Neither Stoy, Byerley nor Chromecek teach or suggest that TEGDMA itself, when polymerized alone, is a "high water content hydrogel forming monomer" or refute Dr. Mentak's statement clearly indicating that TEGDMA is used as a crosslinker.

Absent the teaching or suggestion in Stoy of a third monomer which comprises a high water content hydrogel-forming monomer, the reference fails to anticipate claim 33 and all of it's dependant claims under 35 U.S.C. § 102(b).

Claim 34, which depends on claim 33, contains the additional limitation of the rigid intraocular lens and the foldable hydrated intraocular lens differing in volume by less than about 10%. This is an important aspect of the present invention as it allows the lens to be hydrated without any large change in the size of the lens. This allows lenses to be more easily crafted for intraocular use. The Stoy reference fails to teach or suggest such a limitation. Furthermore, the Examiner has made no assertions that the Stoy reference contains such a disclosure. The Examiner has only asserted that the Stoy reference contains a disclosure relating to the change in weight percent of the hydrated lens, not the volume. As the Stoy reference fails to disclose all of the limitations of claim 34, the reference fails to anticipate the claim under 35 U.S.C. § 102(b).

Additionally, in the Examiner's arguments that claims 33, 34 and 37 are anticipated by Stoy, the Examiner has relied on the teachings of two additional references (Byerley and Chromecek). As stated above, neither of these references are used as the basis for a statutory rejection. Furthermore, only a single reference can be used as the basis of a rejection under 35 U.S.C. § 102(b). Appellants respectfully submit, therefore, that the rejection under 35 U.S.C. § 102(b) in view of Stoy is improper, and should be withdrawn.

In view of the arguments above, Appellants respectfully submit that claims 33, 34 and 37 are patentable over 35 U.S.C. § 102(b) in view of the Stoy reference. Appellants therefore respectfully request that the rejection under 35 U.S.C. § 102(b) be reversed.

II. Claim 35 is patentable over 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) in view of Stoy.

The Examiner rejected claim 35 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, obvious under 35 U.S.C. § 103(a) over Stoy.

Claim 35 depends from claim 33, and therefore contains all of the elements and limitations therein. Claim 35 further contains the additional limitations of "wherein the intraocular lens is a 20 diopter lens and has a central thickness less than about 0.4 mm." (See claim 35).

The Examiner has asserted that as Stoy teaches that at 31.5 diopters the central thickness is 0.73 mm, it holds true that at 20 diopters the thickness should be close the claimed range (20xO. 73/31.5)=0.46. The Examiner has failed to consider, however, the effect of the change in thickness to the refractive index of the lens. Claim 33, upon which claim 34 depends, includes the limitation that the lens has a refractive index greater than about 1.55. While Stoy discloses that a lens at 31.5 diopters, and a thickness of 0.73mm has a refractive index of 1.570, it contains no teaching or suggestion that if the diopters are changed to 20 and the thickness to less than 0.4

mm that the refractive index would remain greater than 1.55. Normally such a decrease in thickness leads to a decrease in the refractive index. Therefore if anything, given the teaching of a refractive index of 1.57 of a lens of .73mm thickness, Stoy would suggest that the refractive index of a lens with a thickness 0.4 mm or lower would be less than 1.55.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Claim 35 contains all of the limitations of claim 33. As discussed above, the Stoy reference fails to disclose a "third monomeric component which comprises a high water content hydrogel-forming monomer". Furthermore, the Stoy reference fails to teach or suggest the making of a 20 diopter lens, with a central thickness less than about 0.4 mm, and a refractive index greater than about 1.55. As the Stoy reference has fails to disclose all of the elements and limitations of claim 35, the reference fails to anticipate claim 35 under 35 U.S.C. § 102(b).

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. *In re* Keller, 642 F.2d 413, 425, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981). In proceedings before the Patent and Trademark Office, the Examiner bears the burden of presenting a prima facie case of obviousness based upon the prior art. *In re* Fritch, 972 F.2d 1260, 1265, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992); *In re* Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1998).

To establish a prima facie case of obviousness the prior art reference, or references when combined, must teach or suggest all of the claim limitations. *In re* Royka, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (CCPA 1974); M.P.E.P. § 706.02(j), 2143.03. Appellants submit that the Examiner has failed to set forth a *prima facie* case of obviousness.

As discussed above, the Stoy reference fails to contain any teaching or suggestion of a monomeric component which is a "high water content hydrogel-forming monomer" or the the making of a 20 diopter lens, with a central thickness less than about 0.4 mm, and a refractive index greater than about 1.55. Absent such a teaching or suggestion by Stoy, the reference cannot be said to provide for *prima facie* case of obviousness under 35 U.S.C. § 103(a).

In view of the arguments above, Appellants respectfully submit that claim 35 is patentable over 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) in view of Stoy. Appellants therefore respectfully request that the rejection under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) be reversed.

III. Claim 36 is patentable over 35 U.S.C. § 103(a) in view of Stoy.

The Examiner has rejected claim 36 under 35 U.S.C. § 103(a) as being obvious over Stoy. Claim 36 is a dependant claim which depends on claim 33, and therefore contain all of the limitations of claim 33. Claim 36 contains additional limitations directed towards hydrating the copolymer. The claim contains the limitations that the copolymer is hydrated by:

> "placing the copolymer in an aqueous solution;
> gradually increasing the temperature of the aqueous solution to about 40°C;
> holding the temperature of the aqueous solution at about 40□C for at least about 10 minutes;
> gradually increasing the temperature of the aqueous solution to about 60°C;
> holding the temperature of the aqueous solution at about 60°C for at least about one hour; and gradually decreasing the temperature of the aqueous solution to about room temperature." (claim 36)

These elements are important to help to obtain an intraocular lens with the desired properties, namely a hydrated intraocular lens having an equilibrium water concentration less than about 10 weight percent, a refractive index greater than about 1.55, and lens dimensions

(optic size, thickness, diameter) which do not change significantly with hydration. Stoy fails to teach or suggest any of the specific hydration parameters of claim 36.

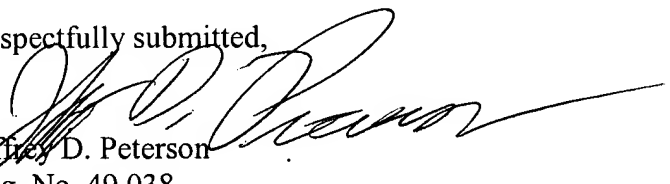
As discussed above, to establish a *prima facie* case of obviousness the prior art reference, or references when combined, must teach or suggest all of the claim limitations. As the Stoy reference fails to contain any teaching or suggestion of a monomeric component which is a "high water content hydrogel-forming monomer", or any of the specific hydration parameters of claim 36, the reference cannot be said to provide a basis for a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

In view of the arguments above, Appellants respectfully submit that claim 36 is patentable over 35 U.S.C. § 103(a) in view of Stoy. Appellants therefore respectfully request that the rejection under 35 U.S.C. § 103(a) be reversed.

9. Conclusion

As outlined above, the Examiner has failed, as a matter of law, to set forth a case of anticipation under 35 U.S.C. § 102(b) in view of Stoy or *prima facie* obviousness under 35 U.S.C. § 103(a) in view of Stoy with respect to the claims of the present invention. Appellants therefore respectfully request that the rejection under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) be reversed.

Respectfully submitted,



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APPENDIX

Listing of Claims

33. (Original) A method of manufacturing an intraocular lens, the method comprising:

a) providing a rigid, hydratable copolymer comprising

a first monomeric component which comprises an aryl acrylate or an aryl methacrylate;

a second monomeric component which comprises a monomer having an aromatic ring with a substituent having at least one site of ethylenic unsaturation, wherein the second monomeric component is other than an acrylate; and

a third monomeric component which comprises a high water content hydrogel-forming monomer,

wherein the copolymer has a glass transition temperature greater than about normal room temperature;

b) forming a rigid intraocular lens having the desired dimensions from the rigid copolymer; and

c) hydrating the copolymer to form a foldable, hydrated intraocular lens,

wherein the hydrated intraocular lens has an equilibrium water concentration less than about 10 weight percent, and a refractive index greater than about 1.55.

34. (Original) The method of claim 33 wherein the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10%.

35. (Original) The method of claim 33 wherein the intraocular lens is a 20 diopter lens and has a central thickness less than about 0.4 mm.

36. (Original) The method of claim 33 wherein the copolymer is hydrated by:

placing the copolymer in an aqueous solution;

gradually increasing the temperature of the aqueous solution to about 40°C;

holding the temperature of the aqueous solution at about 40°C for at least about 10 minutes;

gradually increasing the temperature of the aqueous solution to about 60°C;

holding the temperature of the aqueous solution at about 60°C for at least about one hour; and gradually decreasing the temperature of the aqueous solution to about room temperature.

37. (Original) The method of claim 33 wherein the rigid intraocular lens is formed by cutting a lens from a rigid sheet of the copolymer, and polishing the lens.

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